

Application Serial No. 10/813,214
Response to Office Action mailed July 23, 2007
RCE and Amendment dated October 30, 2007

REMARKS

Claims 50-96 are currently pending. Claims 50 and 72 have been amended to recite that the insertion set is separable from the plunger. Reconsideration is respectfully requested based on the claim amendments and traversals discussed below. No new matter has been added.

The present invention is directed to an injector device assembly that includes a sterile insertion set within the injector housing that may be provided to a patient as a sterile set without any further packaging. The insertion set is positioned within the injector device housing for delivery and is removable from the housing after placement of the insertion set on the patient. The injector device assembly includes a releasable cover for covering the forward end of the housing for assuring sterile conditions within the housing, including the insertion set, prior to removal of the cover. The patient does not need to place an insertion set into the injector or manipulate the insertion set in any way before being able to place the insertion set on the skin.

I. **Claim Rejections Under 35 U.S.C. § 103**

Claims 50-57, 59, 65-68, 72-85 and 93-96 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Funderburk et al. (U.S. Patent No. 6,093,172) in view of Turner et al. (U.S. Patent No. 4,817,603). Claims 50-59, 65-88 and 90-92 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Funderburk et al. in view of Karakashian (U.S. Patent No. 3,937,219).

Applicants respectfully traverse the Examiner's rejection based on Funderburk in view of Turner or in view of Karakashian since the references alone or in combination fail to teach or suggest a sterile insertion set that is separable from the plunger and that the cover member and the device housing assure sterile conditions of the insertion set within the device housing prior to removal of the cover member. To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP § 2142.

Claims 50 and 72 have been amended to recite that the insertion set is separable from the plunger. Turner and Karakashian have been cited by the Examiner as disclosing a removable cap on the forward end of the housing or a sterile cover, respectively. However, neither Turner nor Karakashian teaches or suggests a separable insertion set.

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Instead, both Turner and Karakashian disclose a needle device that remains with the housing.

Funderburk fails to disclose a cover over the forward end of the housing as acknowledged by the Examiner on page 2 of the July 23, 2007 Office Action. In addition, due to the absence of a cover, Funderburk fails to teach or suggest that sterile conditions exist within the housing prior to the removal of the cover. Funderburk also fails to teach or suggest that a sterile insertion set is positioned removably from and within the device housing. Instead, Funderburk is directed to an open-ended injector 10. The patient must manipulate and place a separately provided insertion set 14 having a needle 12 in the injector 10 of Funderburk, further compromising sterility.

Turner and Karakashian fail to make up the deficiencies of Funderburk.

Therefore, Applicants respectfully request that the rejection of claims 50-59, and 65-96 under 35 U.S.C. §103(a) be withdrawn.

II. Allowable Subject Matter

Applicants kindly thank the Examiner for indicating that claims 60-64 are allowed.

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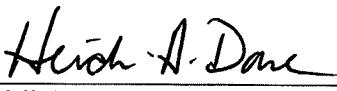
IV. SUMMARY

It is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

October 30, 2007
Date



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